Louisiana Medicaid
Opiate Dependence Agents

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for non-preferred opiate dependence agents.

NOTE: The form should be completed in full, however, for SECTION VI, only the quantity limit information and attestations "C" and "L" are applicable when requesting authorization for opioid dependence agents.

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings** and/or are subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria for Initial and Reauthorization Requests

- For single-ingredient buprenorphine sublingual tablet:
  - The recipient is pregnant; **OR**
  - The recipient has had an *intolerable side effect* to naloxone; **AND**
- For buprenorphine/naloxone sublingual film (generic for Suboxone® sublingual film) – there has been a treatment failure or intolerable side effect with or contraindication to brand Suboxone® sublingual film; **OR**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- If the request is for a non-preferred buprenorphine/naloxone combination product, there is a clinical reason why a preferred buprenorphine/naloxone combination product cannot be used; **AND**
- Previous use - **ONE** of the following is required if the request is **NOT** for a single-ingredient buprenorphine sublingual tablet:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- The requested medication has been prescribed for an approved diagnosis (if applicable – see POS Edits); **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling.

Duration of Initial and Reauthorization Approval for Non-Preferred Opiate Dependence Agents

- **Single-Ingredient Sublingual Buprenorphine for Non-Pregnant Recipients: 4 months**
- **Single-Ingredient Sublingual Buprenorphine for Pregnant Recipients: 6 months**
- **All Other Non-Preferred Opiate Dependence Agents: 6 months**

References

Bunavail® (buprenorphine and naloxone) [package insert]. Raleigh, NC: BioDelivery Sciences International, Inc; March 2021. DailyMed - BUNAVAIL- buprenorphine and naloxone film (nih.gov)

Naloxone injection [package insert]. Lake Forest, IL: Hospira, Inc; September 2019. http://labeling.pfizer.com/ShowLabeling.aspx?id=4541

Naltrexone tablet [package insert]. Webster Groves, MO: Mallinckrodt SpecGX LLC; February 2020. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=06ff2d5a-e62b-4fa4-bbdb-01938535bc65&type=display

Narcan® Nasal Spray (naloxone) [package insert]. Radnor, PA: Adapt Pharma, Inc; February 2017. https://s3-us-west-2.amazonaws.com/narcan-assets-uswest/NARCAN-Prescribing-Information.pdf

Probuphine® (buprenorphine) [package insert]. Princeton, NJ: October 2019. Probuphine-PI-PROAW00009-R1-Oct2019-06Nov2019.pdf (probuphinerems.com)

Sublocade® (buprenorphine) [package insert]. North Chesterfield, VA: AMRI; February 2020. https://www.sublocade.com/Content/pdf/prescribing-information.pdf

Suboxone® (buprenorphine and naloxone) [package insert]. North Chesterfield, VA: Indivior Inc; June 2021. https://www.suboxone.com/pdfs/prescribing-information.pdf

Buprenorphine [package insert]. Eatontown, NJ: Hikma Pharmaceuticals USA Inc; August 2021. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=1bf8b35a-b769-465c-a2f8-099868dfcd2f&type=display

Vivitrol® (naltrexone) [package insert]. Waltham, MA: Alkermes, Inc; March 2021. https://www.vivitrol.com/content/pdfs/prescribing-information.pdf

Zubsolv® (buprenorphine and naloxone) [package insert]. Morristown, NJ: Orexo US, Inc; March 2021. https://www.zubsolv.com/prescribinginformation

REMS

Buprenorphine-containing Transmucosal products for Opioid Dependence (BTOD) REMS https://www.btodrems.com/SitePages/Welcome.aspx

SUBOXONE Film, the Authorized Generic of SUBOXONE Film, SUBOXONE Tablet, and SUBUTEX Tablet REMS http://www.suboxonerems.com/

Revision / Date	Implementation Date
Modified maximum daily dose for buprenorphine/naloxone agents / April 2019	May 2019
Modified quantity limits / June 2019	August 2019
Modified maximum daily dose for buprenorphine agents, added specific wording for use of Suboxone® sublingual film. / October 2019	November 2019
Removed POS information, formatting changes, updated references / May 2020	July 2020
Updated references, formatting changes / October 2021	January 2022